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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,516	HAMMOND ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-75* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-29, and 39 drawn to ligands of the prion protein and compositions thereof, classified in class 436, subclass 543.

II. Claims 40-44, and 56-71, drawn to methods of detecting prions in samples by detecting prion/ligand complexes, classified in class 436, subclass 86.

III. Claims 45-50, and 72-75 drawn to methods of removing prions from samples by removing prion/ligand complexes from the samples, classified in class 424, subclass 344.

IV. Claims 51-55, drawn to methods of treating prion-associated pathologies by administering prion ligands to a subject, classified in class 514, subclass 1.

V. Claims 30-38, drawn to methods of identifying ligands to prion proteins.

For each of inventions I-V above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of inventions I-V and one of inventions (A)-(F)

(A). the ligand is a nucleic acid

(B) the ligand is a polypeptide

(C) the ligand is carbohydrate

(D) the ligand is a lipid

(E) the ligand is an inorganic molecule

The list above is not meant to all-inclusive, it merely recites, in part, the list of potential ligands as disclosed by the applicant. See, app. p. 3-4, crossover paragraph.

For Group IV above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-V, and, if Group IV is elected, then election is also required to one of the prion associate pathologies indicated in claim 53.

The inventions are distinct, each from the others, for the following reasons:

2. Inventions (A)-(E) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as usable together, and each relates to a prion ligand of a different chemical structure, each of which has different mechanics of binding to the prion protein. Because different molecule types and different modes of binding are present, and because the ligands are not disclosed as usable together, the inventions are distinct.

3. The subinventions of Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions each relate to methods of treating different prion associated disorders. Thus, the inventions are not disclosed as usable together, and each of the methods involves the treatment of a different disorder, thereby achieving a different effect and having a different function. The different subinventions of Group IV are therefore unrelated and distinct.

4. Inventions II and III, and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions all relate to different methods of using the same product. Each of the methods performs a different function- the detection of a prion, isolating a prion, and treating prion-associated pathologies. Each of these different types of functions achieves a different effect. As the methods have different purposes, and are not disclosed as usable together, they constitute distinct inventions.

5. Inventions I, and II-IV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Invention I (the prion ligand) is capable of us in several materially different processes (those of Inventions II –IV). Because each of the different processes is materially different from the others for the reasons stated above, and because the product is used in all of them, the product is usable in several materially different processes, and is thus distinct from them.

6. Inventions I and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product is a ligand to prion proteins, and the process is a method of identifying such ligands by running an assay of potential ligands against D-amino acids of a prion protein sequence. However, the ligands to the prion proteins could also be identified through other methods; for

example, the ligands could by identified by detecting in vitro prion inhibition by test agents. Because the ligands may be identified by multiple methods, the method of making in this case is a distinct invention from the product made.

7. Inventions I, II-IV, and V are related as product, process of using, and process of making. Inventions in this relationship can be shown to be distinct if the product can be shown to be distinct from both the process of using and the process of making (MPEP 806.05(i)). As is shown above, the product claims have been shown to be distinct from both the process of making the product and the process of using it. See, above. For those reasons, the product, process of making, and process of using inventions in this application are distinct.

Species Election

8. Groups (A)-(E) above are generic to a plurality of disclosed and/or claimed patentably distinct species. Thus, in addition to the election of one of Groups I-V, and subgroups (A)-(E), the Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from those disclosed in the application, even though this requirement is traversed.

For example, if the Applicant elects subgroup (B) in addition to the election of one of Groups I-V, the Applicant would additionally be required to elect a specific peptide ligand (such as one of those listed in claim 16).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

9. Because these inventions are distinct for the reasons given above, because the literature and sequence searches required for any one of the groups is not required for the others, and because the inventions have divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

10. Applicant is advised that in order for the reply to this requirement to be complete, it must include an election of an invention to be examined as described above, even if the requirement is traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. It is here noted that some of the restrictions requirements made above fall within the scope of PTO Linking claim practice. In accordance with this practice as described in MPEP 809.03, linking claims will be considered with the elected invention. If the elected invention is found allowable, the linking claim will also be examined. If no substantive rejection is found for the linking claim, the restriction among the Groups it comprises will be withdrawn. Currently, claim 1 is considered a linking claim to the various inventions of Group I.

13. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re*

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

James C. Housel 2/7/05

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